October 17, 2012 **This Report CONTAINS Confidential Business Information**

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CONFIRMATION OF RECEIPT REQUESTED

Document Control Office (7407M)
U.S. Environmental Protection Agency
Attn: TSCA Section 8(e) Coordinator
Office of Pollution Prevention and Toxics
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

SUBJECT: TSCA 8(e)SUBMISSION

Dear Sir or Madam:

( ) is submitting certain data which we believe to be reportable under TSCA 8(e). The information concerns ( ), an experimental pyrethroid insecticide. is identified by IUPAC as:

The CAS number assigned for this compound is

has imported for R&D on behalf (" ").

The following reports concerning have been submitted to your agency: Two acute oral toxicity studies with rats (November 15, 2007: 8EHQ-07-16995 & 16996); a preliminary development toxicology study with rats (January 7, 2008: 8EHQ-08-17027); a micronucleus study with rats (February 19, 2008: 8EHQ-08-17081); an acute inhalation toxicity study in rats (July 11, 2007: 8EHQ-08-17209); a two week oral toxicity study in dogs (October 9, 2008: 8EHQ-08-17297); a micronucleus study with rats (February 16, 2010: 8EHQ-10-17866): an in-vivo unscheduled DNA synthesis (UDS) assay in rat hepatocytes (April 5, 2010: 8EHQ-10-17907); effects on pre- and postnatal development, including maternal function in rats (May 21, 2010: 8EHQ-10-17958); an in-vivo unscheduled DNA synthesis (UDS) assay in female rat

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hepatocytes (May 21, 2010: 8EHQ-10-17957); an acute oral toxicity study in rats (August 26, 2010); and a thirteen week repeated dose oral (feeding) toxicity study in Wistar rats (8EHQ-10-18166).

recently learned of new toxicological effects in a 28 day dose range finding oral (dietary) immunotoxicity study with rats. An outline of the study follows:

; 28 day dose range finding dietary immunotoxicity study with rats
was administered to male rats in feed at dose levels of 3000 and 6000ppm (238 and 502 mg/kg/day) for four weeks.

Decreased body weight and body weight gain were observed at 3000 and 6000ppm. Therefore, the NOAEL for general toxicity is lower than 3000ppm (238 mg/kg/day).

believes that these clinical signs are reportable under TSCA 8(e).

Performing Laboratory

Study methods:
Test substance: (Lot #)
Animals: Crl:WI(HAN) rats; males, 8 animals/group
Animal age at initiation of treatment: approximately 7 weeks
Body weight range at initiation of treatment: males. 184 to 213 g
Administration route: orally in the diet
Dose levels: 3000 and 6000ppm (238 and 502 mg/kg/day)
Vehicle: rodent maintenance diet
Treatment period: 4 weeks
Observation items: Clinical observations, detailed clinical observations, body weight, food consumption, necropsy, absolute organ weights, relative organ weights, and T-dependent antibody response assay (AFC)

Results:
Decreased body weight and body weight gain were observed at 3000 and 6000ppm. Therefore, the NOAEL for general toxicity is lower than 3000ppm (238 mg/kg/day). This result suggests that the NOAEL could be lower than 200 mg/kg/day if the rats are dosed for a period of four weeks or shorter than four weeks.

next conducted a 28 day Oral (dietary) immunotoxicity study with male Wistar Han rats.
; 28 day dietary immunotoxicity study with rats
was administered to male rats in feed at dose levels of 300, 1000, and 3000ppm (26, 81, and 241 mg/kg/day) for four weeks.

Decreased body weight, body weight gain, and food consumption were observed at 3000 ppm; however, in the absence of -related effects on the AFC response. Therefore, the NOAEL for general toxicity is judged to be 1000ppm (81 mg/kg/day) and the NOAEL for the humoral immune response is considered to be 3000ppm.

Since the NOAEL was lower than 200 mg/kg/day in a dosing period for four weeks or shorter, believes these clinical signs are reportable under TSCA 8(e).

Performing Laboratory:

Study methods:
Test substance: (Lot #)
Animals: Crl:WI(HAN) rats; males, 10 animals/group
Animal age at initiation of treatment: approximately 7 weeks
Body weight range at initiation of treatment: males: 181 to 224 g
Administration route: orally in the diet
Dose levels: 300, 1000, and 3000ppm (26, 81, and 241 mg/kg/day)
Vehicle: rodent maintenance diet
Treatment period: 4 weeks
Observation items: Clinical observations, detailed clinical observations, body weight, food consumption, necropsy, absolute organ weights, relative organ weights, and T-dependent antibody response assay (AFC)

Decreased body weight, body weight gain, and food consumption were observed at 3000ppm; however, in the absence of -related effects on the AFC response. Therefore, the NOAEL for general toxicity is judged to be 1000ppm (81 mg/kg/day) and the NOAEL for the humoral immune response is considered to be 3000ppm.

Substantiation of CBI Claims

We wish to substantiate claims that certain information in this letter be treated as Confidential Business Information ('CBI'). All information which has been deleted from the sanitized version of this letter (copy attached) should be treated as CBI. In substantiation of this CBI claim, wishes to protect its confidential business plan for the commercial development of this compound. Disclosure of this information would harm efforts to commercialize this compound. Please refer to the attached letter of March 17, 2010 to Mr. Edward Gross regarding substantiation of CBI claims.

If there are any questions on this submission please feel free to contact me at (410-747-4500).

Yours sincerely,

Technical Consultant

Encl.
cc: